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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,683

Applicant(s)

Cevc

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 12-11-01 and 1-25-02

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 22-33 and 49-90 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 22-33 and 49-90 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17-20

20) ☐ Other:

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DETAILED ACTION

The request for the extension of time and notice of appeal dated 8-24-01, the request for the extension of time, filing under 1.53 (d) and the preliminary amendment dated 11-20-01 are acknowledged.

Claims included in the prosecution are 22-33 and 49-90.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 22-33 and 49-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 22 is a method of preparation claim and therefore should recite method step leading to the formation of transfersomes. Step a recites selecting the lipid components and step b recites suspending the transfersome. There is no step in the claim as to how the transfersomes are formed. This is critical in view of applicant's assertion that transfersomes are different from liposomes. The distinction between the pharmaceutically acceptable medium in step a and the solubilizing agents in step c is unclear. Also unclear as

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to how one can adjust the amphiphilic lipid components once the transfersomes are formed as recited in step d. This claim does not recite an active agent at all though the preparation is for the transport of the active agent. The examiner suggests a thorough revision of this claim.

It is unclear as to how one can determine the permeability through skin by filtration or other methods recited in claim 24. What is being conveyed by 'under pressure'? What is subjected to under pressure? 'Fine' in fine pored filter is indefinite; fine is a relative term.

'other mechanical comminuting effects' in claim 25 is indefinite; other is not a positive expression; specific methods should be recited.

The distinction between the polar liquid recited in claim 26, pharmaceutically acceptable medium and the solubilizing agents recited in claim 22 is unclear.

What is meant by 'optionally brought into solution' as recited in claim 28? If they are brought into solution, then how are transfersomes formed? Similar is the case with claim 29.

What is meant by 'rubbing' in claim 30? The terms, 'low' and 'high' are relative terms. The temperature units should be recited for 'heating' and 'cooling' in claim 30.

What is prepared from a concentrate as recited in claim 33?

What is meant by 'reference particle' in claim 50? This term lacks an antecedent basis in claim 23.

Claim 52 is not further limiting claim 31 in terms of pore sizes.

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It is unclear whether the claim 53 is a treatment claim or transport claim. If it is a treatment claim, the condition of the mammal to be treated should be recited.

What is being conveyed by ‘more soluble amphiphilic component is an active ingredient’ as recited in claim 68? According to the parent claim 53, the active agent is separate from the two amphiphilic lipids.

Claim 73 recites a glyceride, a steroid and a sterol as amphiphilic lipid components. It is unclear how these can be considered as amphiphilic. What is meant by ‘half protonated liquid fatty acid’?

Claim 84 recites numerous active agents and the meaning of some of which is unclear. For example, ‘a sleeping draft’, ‘a sleeping draft antagonist’, ‘bioactive carbohydrate’, ‘mineral corticoid’, ‘a biological activity inhibitor’, ‘coenzyme inhibitor’ to name a few. Applicant should go through the list carefully and submit evidence to show that these are known terms. Furthermore, the claim recites, generic terms in terms of anti-disease agents and some specific compounds. There is considerable overlapping of the compounds. The examiner suggests a careful revision of this claim.

What is being conveyed by ‘growth regulating substance’ as recited in claim 87?

‘Active ingredient’ in claim 84, 85, and 87- 89 lacks an antecedent basis in claim 53.

It is unclear what the allurements allures as recited in claim 89.

The examiner suggest a very careful revision of all the claims pending in the application.

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Claim Rejections - 35 U.S.C. § 102

- 2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 3. Claims 22-33 and 49-90 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 475 160 of record.**

EP discloses instant composition containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation (see the entire document).

Applicant's arguments have been fully considered, but are found to be persuasive. Applicant argues that this reference is cited in the international search report as defining the general state of the art and which is not considered to be of particular relevance to the present invention. However, applicant also indicates that this EP reference corresponds to

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US 6,165,500. Since this US patent discloses the same composition, the rejection is applicable.

Claim Rejections - 35 U.S.C. § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 5. Claims 22-33 and 49-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 475 160 cited above.**

As pointed out above, EP teaches a composition containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation. It is unclear whether the reference teaches all the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulatable by an artisan to obtain the best possible results.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 8, 2002